UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,997	12/05/2001	John W. Sliwa	003-007-C4	5763

7590 03/26/2003

HOEKENDIJK & LYNCH, LLP
P.O. Box 4787
Burlingame, CA 94011-4787

EXAMINER
PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/008,997	Applicant(s) SLIWA ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-81* is/are pending in the application.

4a) Of the above claim(s) *61-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Claims 61-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Priority

It is noted that in addition to the applications recited in the Cross Reference to Related Applications section of the specification there are numerous other co-pending applications which disclose and claim very similar and/or identical subject matter. In accordance with 37 CFR 1.105 and MPEP 704.11(a) subsection G, applicant is respectfully requested to disclose all co-pending applications and related patents and identify the specific claims of those applications and/or patents which may present double patenting issues with the instant application claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 78 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 lacks proper antecedent basis for "the focus". It appears this claim should depend from claim 77 which provides proper antecedent basis, and not from claim 74.

Claims 78 and 79 are also unclear in the scope of the claim. These claims

positively recite the body by reciting the system moves the focus relative to tissue. Language such as "the control system is adapted to move the focus relative to the tissue" is suggested to avoid the positive recitation of tissue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74 and 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Cain et al ('657).

Cain et al disclose an ultrasonic ablation system which provides focused ultrasound energy for the ablation of tissue (Abstract). There is an ablating element (16) and a control system to control the output of the ablation element in response to sensed parameters. Column 6, line 6 through Column 7, line 54 discusses the use of the control system to vary the focus of the energy to appropriately treat tissue. The steps of focusing in at least one direction and moving the focus relative to tissue would inherently be performed by the system as necessitated by the conditions.

Claims 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al ('280).

Sherman et al disclose an ultrasound catheter ablation system for treating tissue. The catheter is delivered to cardiac tissue and ultrasonic energy is emitted to create lesions in tissue (Abstract). Tissue conditions (i.e. temperature) are monitored and a control system (174 – Figure 10) is used to control the power and frequency of the ablating element(s). Column 4, lines 1-35 address the control of the power level and frequency ranges.

Claims 74 and 76-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Hissong ('531).

Hissong discloses a device comprising an ablating element (26) and a control system (16) for controlling the focus of the ultrasonic energy (Abstract). Column 14 addresses the use of the controller vary the power level, and column 15, lines 40+ address the use of the controller to move the focus of the energy. The steps of focusing in at least one direction and moving the focus relative to tissue would inherently be performed by the system as necessitated by the conditions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman ('280) in view of the teaching of Hissong ('531).

The Sherman system has been addressed previously. While Sherman discloses a controller for controlling the frequency and power of the ablating element, there is no specific disclosure of controlling the focus of the ultrasonic energy.

Hissong discloses an analogous system for ablation of tissue with ultrasonic energy. In particular, Hissong disclose the use of a controller which controls the power delivery and the focus of the ultrasonic to effectively treat target tissue over a large area.

To have provided the Sherman system with means to control the focus of the ultrasonic energy to treat a larger area more effectively would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Hissong.

Claims 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Sherman ('280) or Hissong ('531) in view of the teaching of Marcus et al ('484).

The Sherman and Hissong devices have been addressed previously. There is no disclosure in either of these references of a means in the control system for assessing the adequacy of contact of the device and the target tissue.

Marcus et al disclose an analogous device for the ablation of cardiac tissue with ultrasonic energy. In particular, Marcus et al provide a control system which receives mapping data from electrodes located near the transducers for locating the target

tissue. Further, the device is provided with a temperature sensor to determine if the transducer is in contact with tissue (column 4, lines 64-68).

To have provided either the Sherman or Hissong controllers with a means to assess tissue contact of the ablation device prior to the treatment of tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Marcus et al.

Double Patenting

The pending claims of this application may conflict with select claims of one or more of the following Application Nos.: 09/606,742; 09/954,393; 09/507,336; 09/698,639; 09/699,150; 09/698,357; 09/614,991; 09/884,435; 10/171,411; 10/171,390; 10/172,732; 10/171,389; 10/232,963; 10/232,964; 10/010,409; 10/006,064; 10/008,904; 10/006,088; 10/077,470; 10/238,821; 10/238,937; 10/255,134. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The currently pending claims of this application are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of select claims of one or more of copending Application Nos. 09/606,742; 09/954,393; 09/507,336; 09/698,357; 09/698,639; 09/699,150; 09/614,991; 09/884,435; 10/171,411; 10/171,390; 10/172,732; 10/171,389; 10/232,963; 10/232,964; 10/010,409; 10/006,064; 10/008,904; 10/006,088; 10/077,470; 10/238,821; 10/238,937; 10/255,134. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The currently pending claims of this application are rejected under 35 U.S.C. 101 as claiming the same invention as that of select claims of one or more of prior U.S. Patent Nos. 6,161,543; 6,237,605; 6,311,692; 6,314,962; 6,314,963; 6,484,727; 6,474,340. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The currently pending claims of this application are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over select claims of one or more of U.S. Patent Nos. 6,161,543; 6,237,605; 6,311,692; 6,314,962; 6,314,963; 6,484,727; 6,474,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because the various method steps and device parameters are deemed obvious.

The currently pending claims of this application are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over select claims of one or more of copending Application Nos. 09/606,742; 09/954,393; 09/507,336; 09/698,357; 09/698,639; 09/699,150; 09/614,991; 09/884,435; 10/171,411; 10/171,390; 10/172,732; 10/171,389; 10/232,963; 10/232,964; 10/010,409; 10/006,064; 10/008,904; 10/006,088; 10/077,470; 10/238,821; 10/238,937; 10/255,134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the various method steps and device parameters are deemed obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

It is noted that applicant has filed literally thousands of claims in the dozens of related applications/patents. Many claims are canceled/added to each application, and there is a substantial repeat of claimed subject matter in many of the applications. The

above double patenting rejections are an effort to discern what is effectively being claimed in each application and ensuring that overlapping subject matter is not issued in multiple patents. Applicant is reminded of the requirement to address each rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mills et al ('509) disclose an ultrasonic ablation device which includes a feedback control system, and Tu ('024) discloses an ultrasonic ablation catheter for the ablation of tissue. Martin et al discloses the use of focused ultrasonic energy for the treatment of tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
March 19, 2003

JOHN E. KITTLE
DIRECTOR TC 3700